Upfront 2-Stent; New Concept in LM Bifurcation PCI

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support

- Consulting Fees/Honoraria

- Stock shareholder:

Company

- Abbott Vascular, Boston Scientific, HeartFlow, Inc, MVRx

- Amgen, Abbott Laboratories, Astra-Zeneca, Bayer, Boehringer Ingelheim, GlaxoSmithKline, Berlin Chemie / Menarini, Merck, Pfizer, Roche, Sandoz, Sanofi, Servier Laboratories, Siemens laboratories, Abbott Vascular, Boston Scientific, Biotronik, Biosensors, Cordis,

- CERC

Backgroud

- Although the 1-stent strategy is generally considered the default strategy for bifurcation lesions, there are some scenarios in which the 2-stent strategy is initially necessary to guarantee the patency of both the main branch and the side branch.

- High occurrence of in-stent restenosis of the left circumflex artery ostium has been considered the major limitation of percutaneous coronary intervention for unprotected left main lesions disease when using 2-stent strategy.

Hypothesis and Objectives

- Hypothesis: The novel method for the treatment of distal ULMCA true bifurcation stenosis is safe and feasible.

- Objectives: The study aimed to investigate long-term outcomes of an IVUS-guided and OCT-optimized double stent-scaffold technique (Mini-crush or T-stent strategy) in patients with true LM bifurcation lesions involving the LCX ostium, utilizing a drug-eluting stent (DES) in the LM extending into the left anterior descending artery (LAD) and a bioresorbable vascular scaffold (BVS) in the LCX ostium.

Methods

- A single-center, prospective, single-arm study of 46 consecutively enrolled patients with stable coronary artery disease and significant unprotected LM distal bifurcation disease.

- The primary outcome at four years was the composite of death, myocardial infarction, stroke, and target lesion revascularization (TLR).
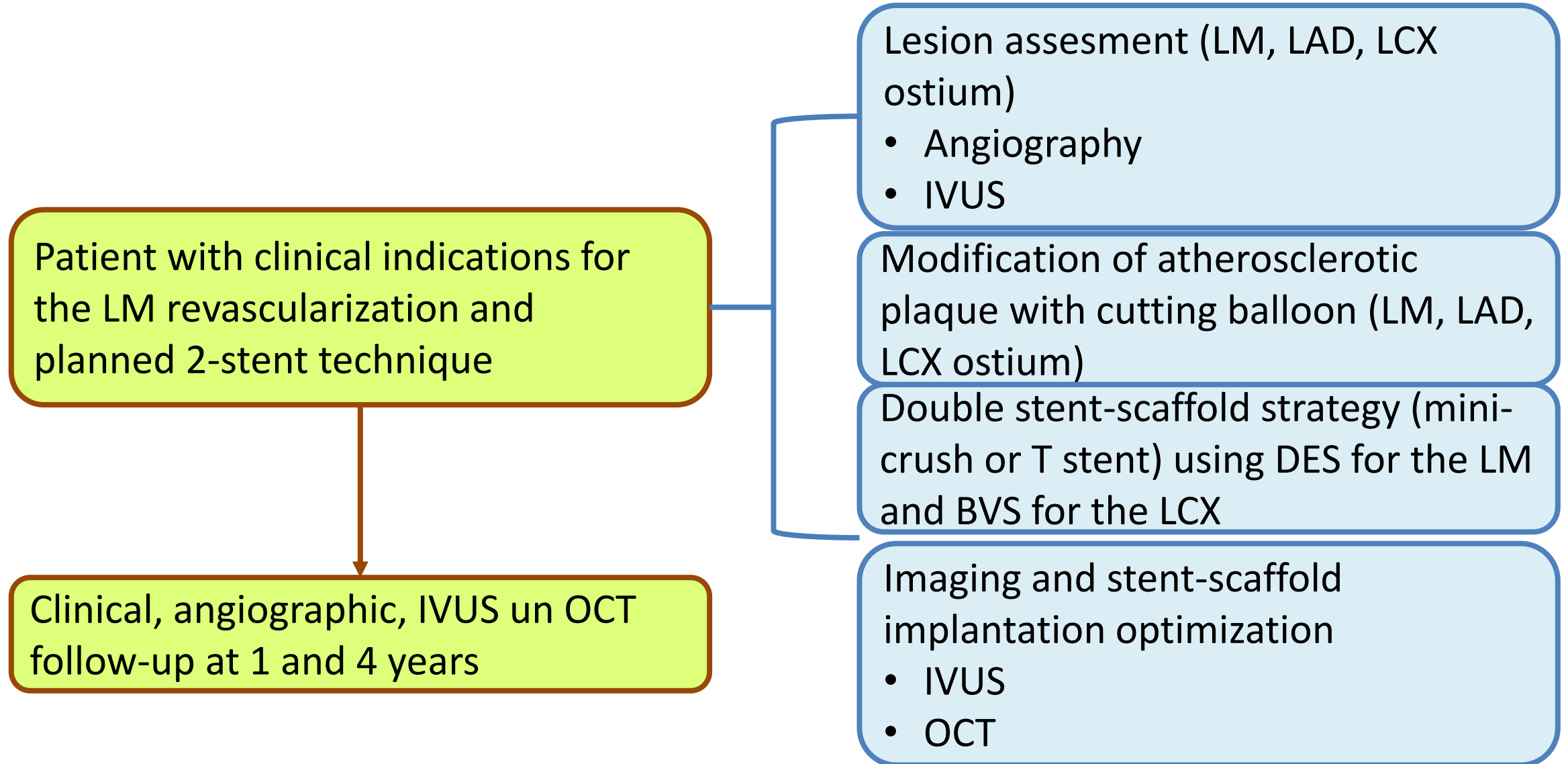
Main inclusion criteria:

Patients age >18 years with stable coronary artery disease

True left main bifurcation lesions
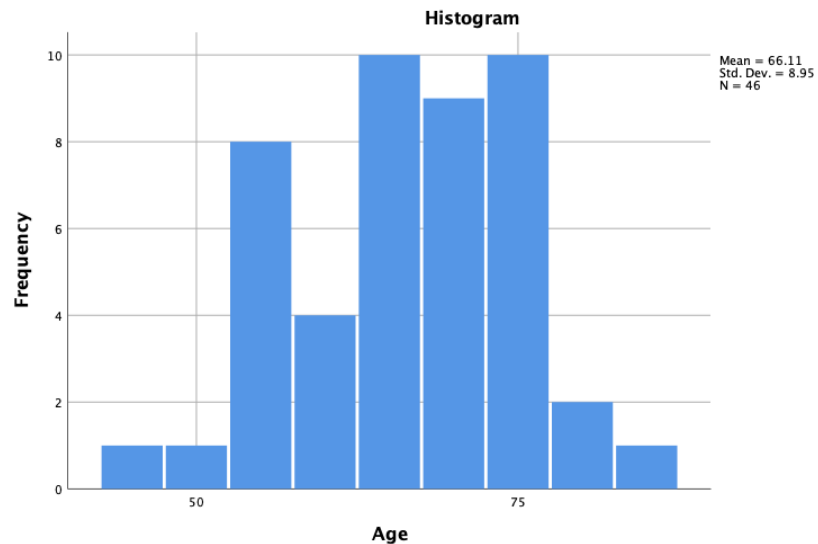
Planned 2-stent strategy

Main exclusion criteria:

Acute myocardial infarction

Anaemia (Hb<9 g/dl)

Suspected intolerance to 1 of the study drugs

Flow chart

Patient with clinical indications for the LM revascularization and planned 2-stent technique

Clinical, angiographic, IVUS un OCT follow-up at 1 and 4 years

Lesion assesment (LM, LAD, LCX ostium)
- Angiography
- IVUS

Modification of atherosclerotic plaque with cutting balloon (LM, LAD, LCX ostium)

Double stent-scaffold strategy (mini-crush or T stent) using DES for the LM and BVS for the LCX

Imaging and stent-scaffold implantation optimization
- IVUS
- OCT

Baseline patient characteristics

Mean age: 66.1 ± 8.9 years
(min-max 45-86 years)

Characteristics	All patients (N = 46)
Age, years	66.1 ± 8.9
Male gender	34 (73.9)
Hypertension	44 (95.7)
Dyslipidemia	40 (87.0)
Diabetes mellitus	6 (13.0)
Current Smoking	13 (28.3)
Prior myocardial infarction	14 (30.4)
Prior percutaneous coronary intervention	21 (45.7)
Prior coronary artery bypass graft	0 (0)
Chronic Heart failure	29 (63.0)
Peripheral artery disease	6 (13.0)
Family history of cardiovascular disease	12 (26.1)
Total cholesterol, mmol/l	4.0 ± 0.9
Low-density lipoprotein (LDL) cholesterol, mmol/l	2.2 ± 0.8
Left ventricular ejection fraction, %	57.1 ± 9.2
Syntax Score	23.2 ± 5.3
Categorical variables are expressed as numbers and percentages. Continuous variables are indicated as mean ± SD.	

Baseline lesion characteristics

Syntax score: 23.2 ± 5.3 (min-max 14-36)
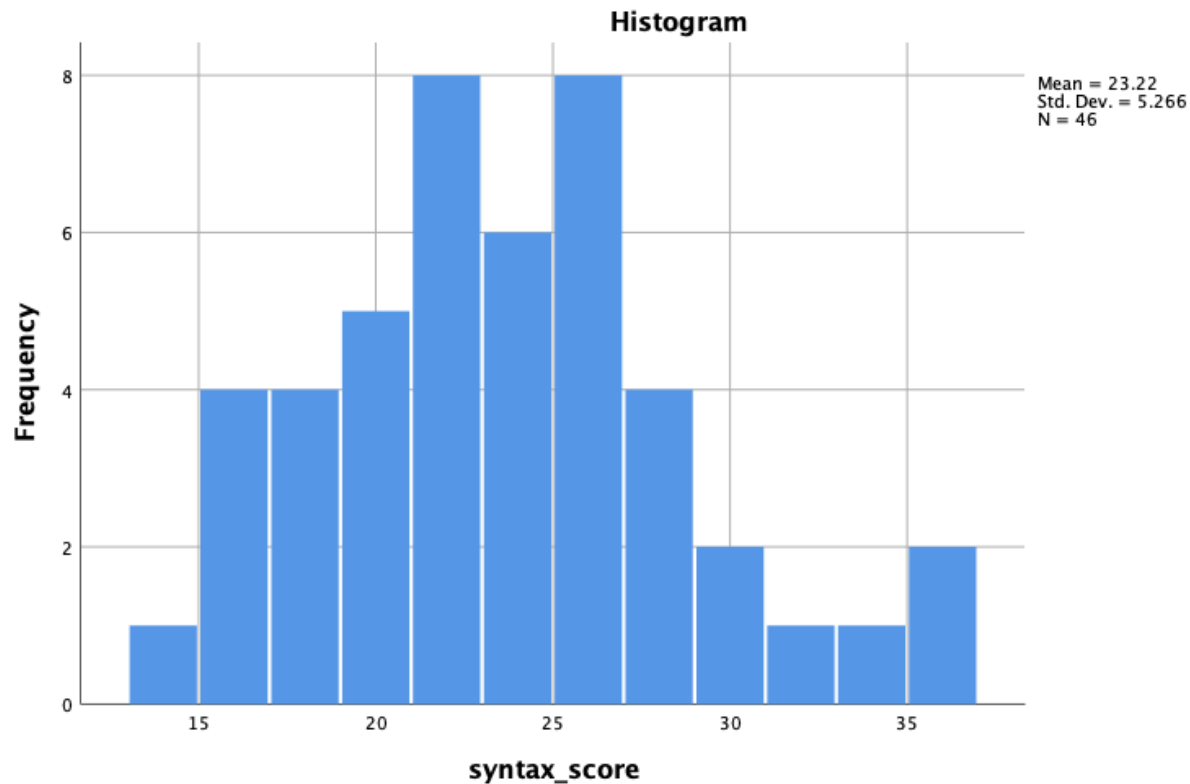
Distal left main true bifurcation lesions

(Medina 111, 101, 011) - 46 (100)

Histogram

Mean = 23.22
Std. Dev. = 5.266
N = 46

Procedural characteristics

Characteristics Values ar mean ± SD or n (%)	All patients (n=46)
Transradial approach	16 (34.8)
7-F guiding catheter	34 (73.9)
Pre-procedure IVUS	
Main branch	42 (91.3)
Side branch	42 (91.3)
Pre-procedure OCT	
Main branch	4 (8.7)
Side branch	4 (8.7)
Cutting balloon predilatation	
LM-LAD	39 (84.8)
LCX	36 (78.3)
Cutting balloon diameter, mm	
Main branch	3.4 ± 0.3
Side branch	3.2 ± 0.3
Stenting technique	
T-stent	14 (30.4)
Mini-crush	32 (69.6)

Characteristics Values ar mean ± SD or n (%)	All patients (n=46)
Stent	
LM-LAD: Synergy	42 (91.3)
LM-LAD: non-Synergy DES	4 (8.7)
LCX: Absorb	46 (100.0)
Stent diameter, mm	
Main branch	3.8 ± 0.3
Side branch	3.1 ± 0.4
Stent length, mm	
Main branch	22.5 ± 7.3
Side branch	15.8 ± 4.8
Final kissing balloon postdilatation	42 (91.3)
Post-procedure IVUS	
Main branch	(40 (87.0)
Side branch	(40 (87.0)
Post-procedure OCT	
Main branch	42 (91.3)
Side branch	42 (91.3)
Complications	5 (10.9)
Dissection	3 (6.5)
Groin hematoma	2 (4.4)
Procedural success	46 (100.0)

Major adverse cardiac events (1 year)

- Mean follow-up at 1 year: 380 ± 93 days
  - Angiographic 41 (89.1%)
  - By phone 5 (10.9%)
- DAPT for 12 months: 46 (100.0%)
  - Clopidogrel 28 (60.9%)
  - Ticagrelor 18 (39.1%)
- Myocardial infarction resulting from stent thrombosis occurred 30 days after index procedure. Successfully treated by PCI

| Cumulative events at 1 year	All patients (n=46)
Death, n (%)	0 (0.0)
Cardiovascular death, n (%)	0 (0.0)
Myocardial infarction, n (%)	1 (2.2)
Stroke, n (%)	0 (0.0)

Target lesion revascularization, n (%)
    LM-LAD DES restenosis
    LCX BVS restenosis
    LCX BVS stent thrombosis
	7 (15.2)
	 0 (0.0)
	 6 (13.0)
	 1 (2.2)

Stent thrombosis	1 (2.2)
MACE (death, myocardial infarction, stroke, TLR)	7 (15.2)

Major adverse cardiac events (4 year)

- Mean follow-up at 4 year: 4.1 years ± 4.2 months
- Angiographic 33 (71.7%), by phone 13 (28.3%)

Survival free from MACE

Cumulative events at 4 years	All patients (n=46)
Death, n (%)	0 (0.0)
Cardiovascular death, n (%)	0 (0.0)
Myocardial infarction, n (%)	1 (2.2)
Stroke, n (%)	0 (0.0)
Target lesion revascularization, n (%)	9 (19.6)
LM-LAD DES restenosis	1 (2.2)
LCX BVS restenosis	7 (15.2)
LCX BVS stent thrombosis	1 (2.2)
Stent thrombosis	1 (2.2)
MACE (death, myocardial infarction, stroke, TLR)	9 (19.6)
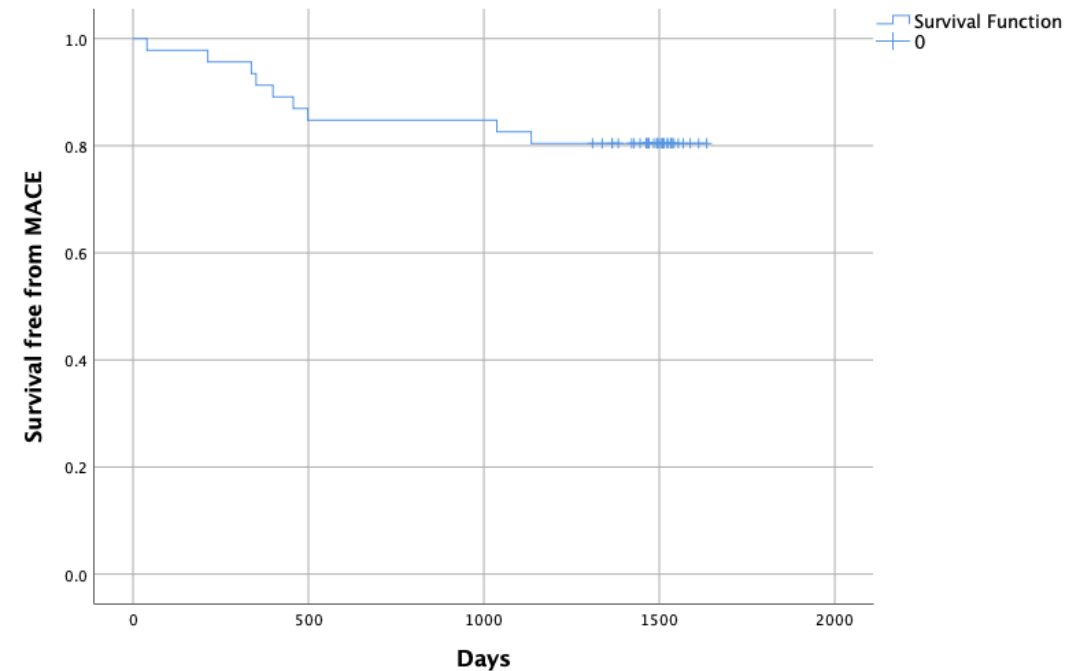
Predictors of MACE at 4 years

MACE (death, myocardial infarction, stroke, TLR)

Variable	MACE +	MACE -	Hazard ratio (95% CI)	p value
Total cholesterol	**4.8 ± 1.2**	**3.9 ± 0.8**	**2.839 (1.169-6.897)**	**0.021**
Low density lipoprotein	**3.0 ± 1.0**	**2.1 ± 0.7**	**3.918 (1.396-10.996)**	**0.009**
Side branch plaque modification with cutting balloon	**4 (44.4%)**	**32 (86.5%)**	**0.125 (0.025-0.630)**	**0.012**
Absorb scaffold diameter ≤ 2.5 mm at the LCX ostium	**4 (44.4%)**	**5 (13.5%)**	**5.120 (1.016-25.813)**	**0.048**
No post intervention IVUS MB	**4 (44.4%)**	**2 (5.4%)**	**14.000 (2.014-97.311)**	**0.008**
No post intervention IVUS SB	**4 (44.4%)**	**2 (5.4%)**	**14.000 (2.014-97.311)**	**0.009**

MACE was not predicted by:
Clinical: Age, Gender, Hypertension, Dyslipidemia, Diabetes, Smoking, Family history, Prior MI, Prior PCI, HF, PAD, EF
Angiographic: Syntax score
Procedural: Pre-IVUS, Pre-OCT, CB in the MB, CB MB diameter, CB SB diameter, Stenting technique, LM DES diameter, Absorb diameter, LM DES length (p=0.068), Absorb length, FKPD, Post-OCT

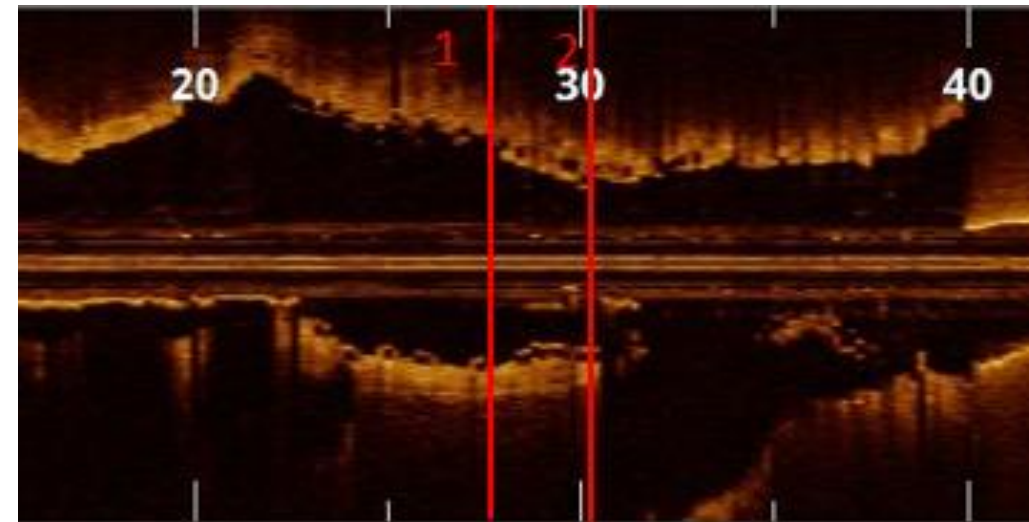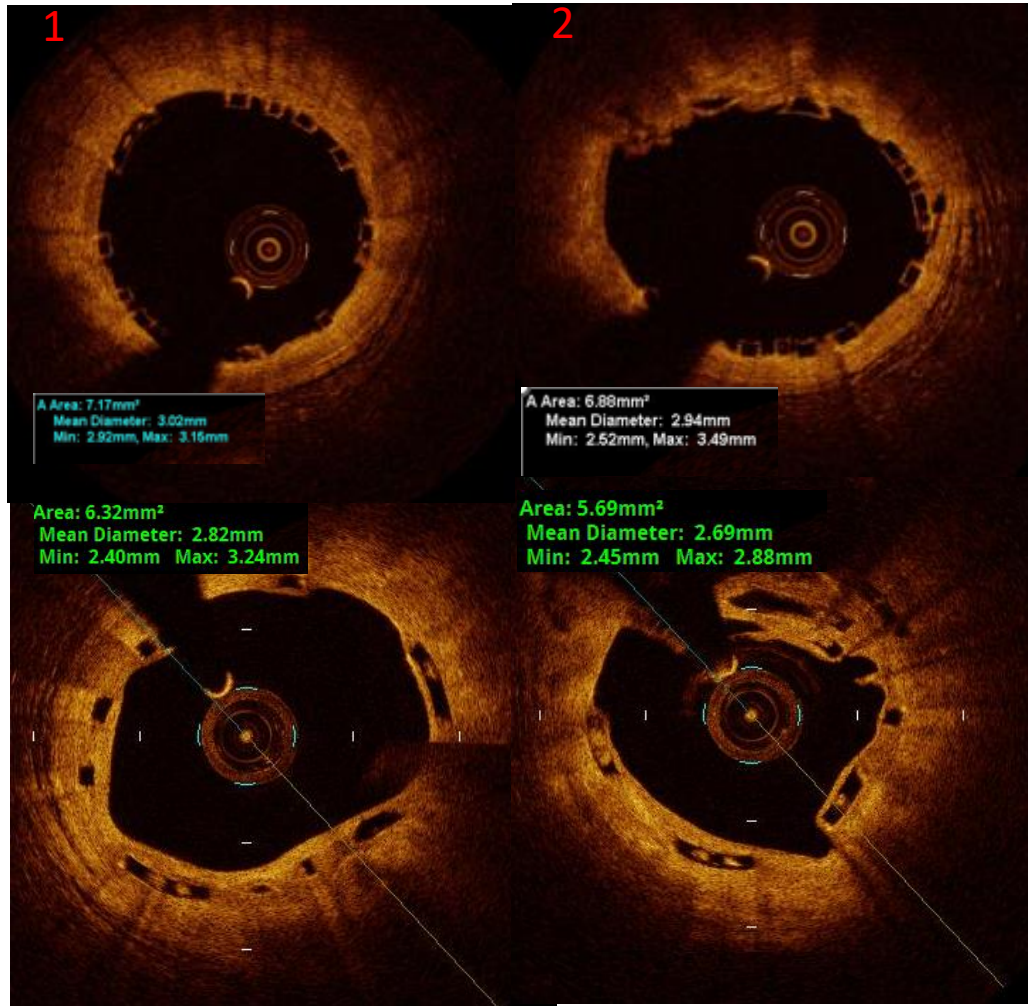Univariate logistic regression was used to determine the predictors of MACE.

Conclusion

- The use of a hybrid 2 stent/scaffold strategy with DES in the main branch and BVS in the side branch in selected patients with LM true bifurcation disease was technically possible and was reasonably safe and effective.

- The incidence of major events at short and long-term follow-up was similar to published series of treatment with a two DES stent strategy.

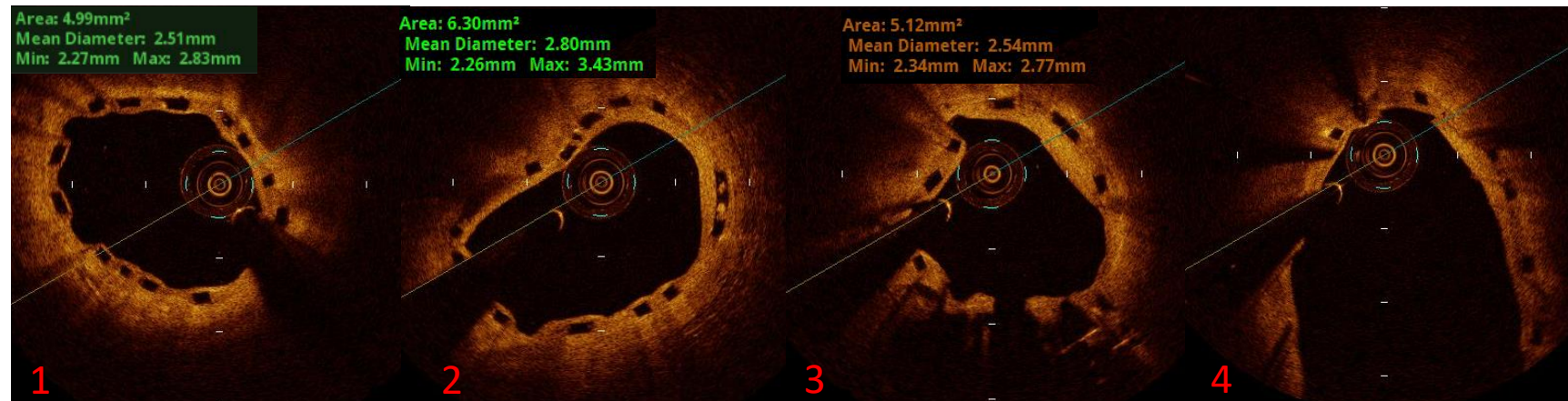- Further, larger scale and randomized studies are required.

Erglis A, et al. J Interv Cardiol. 2022 Oct 31;2022:7934868.

When two becomes one ….

OCT of LCX after intervention and 1 year follow up

Pilot study, Patient No 18